SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

January 10, 2011
Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-26422**	**94-3171943**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
(Address of principal executive offices)

(215) 488-9300
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. **Other Events.**

On January 10, 2011, Discovery Laboratories, Inc. (the "Company") issued a press release providing an update regarding its efforts to file a Complete Response intended to gain U.S. Food and Drug Administration ("FDA") marketing authorization of Surfaxin® for the prevention of respiratory distress syndrome ("RDS") in premature infants. The Company has had multiple interactions with the FDA regarding various aspects of the final validation of an important quality control release and stability test for Surfaxin, the fetal rabbit biological activity test ("BAT"). In response to a proposal submitted by the Company, the FDA has recently provided detailed, written direction regarding the verification of certain parameters related to final BAT validation. The FDA indicated that several aspects of the Company's proposed approach to the BAT validation are reasonable; however, with respect to certain parameters, the FDA is requesting additional data to further support ultimate determination of BAT validation. Based on the Company's preliminary assessment, it believes that it could generate the additional data and be in a position to file a Surfaxin Complete Response by early third quarter 2011, which potentially could lead to approval of Surfaxin for the prevention of RDS in premature infants early in the first quarter 2012.

The press release is attached as Exhibit 99.1 hereto and the text of the press release is incorporated herein by reference to such exhibit.

The information in this Form 8-K includes certain "forward-looking" statements relating, among other things, to the Company's understanding of the recently-received written guidance from the FDA and the remaining questions identified in the FDA's April 2009 Complete Response Letter that must be addressed to gain FDA approval of Surfaxin. Although the Company currently believes that it may still succeed in submitting a Complete Response and gaining approval of its New Drug Application for Surfaxin for the prevention of RDS in premature infants, anticipated activities will require that the Company raise significant amounts of additional capital. The Company has initiated activities relating to this most recent FDA communication and anticipates potential further interactions with the FDA in advance of filing a Complete Response. Such potential interactions with the FDA could affect the ultimate timing, conduct and outcomes of remaining steps necessary to gain Surfaxin approval, including the potential filing of the Complete Response. In addition, these activities and the ultimate outcomes remain subject to a variety of risks and uncertainties that could cause actual results to be materially different. These risks and uncertainties include, but are not limited to, risks that (i) the FDA may not accept the additional data or may interpret the data in a different manner such that, ultimately, the FDA may not approve Surfaxin or that the FDA may subject the marketing of Surfaxin to onerous requirements that significantly impair marketing activities; (ii) the Company may be unable to complete the manufacture of additional Surfaxin batches to address the FDA's request for additional data in a timely manner, (iii) the Company may identify unforeseen problems that have not yet been discovered or the FDA could in the future impose additional requirements to gain approval of Surfaxin; (iv) the Company may be unable to raise sufficient additional capital, through financings, strategic collaborations, or otherwise; and (v) other risks included in the Company's most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Any failure to satisfy the issues raised by the FDA, in the Complete Response letter or in related discussions, could significantly delay, or preclude outright, gaining approval of Surfaxin, which could potentially delay or prevent the approval of the Company's other products and would have a material adverse effect on the Company's business.

Item 9.01. **Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press release dated January 10, 2011

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in this Current Report on Form 8-K are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such risks and others are further described in the Company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Discovery Laboratories, Inc.

By: /s/ W. Thomas Amick

Name: W. Thomas Amick

Title: Chairman of the Board and Chief Executive Officer

Date: January 10, 2011

Exhibit 99.1

Discovery Labs Provides Update Regarding its Program for Surfaxin® U.S. Marketing Authorization

Warrington, PA — January 10, 2011 — Discovery Laboratories, Inc. (Nasdaq: DSCOD), a biotechnology company developing its novel, synthetic, peptide-containing surfactant, is providing an update regarding its efforts to file a Complete Response intended to gain U.S. Food and Drug Administration (FDA) marketing authorization of Surfaxin® for the prevention of respiratory distress syndrome (RDS) in premature infants. Discovery Labs has had multiple interactions with the FDA regarding various aspects of the final validation of an important quality control release and stability test for Surfaxin, the fetal rabbit biological activity test (BAT). In response to a proposal submitted by Discovery Labs, the FDA has recently provided detailed, written direction regarding the verification of certain parameters related to final BAT validation. The FDA indicated that several aspects of Discovery Labs' proposed approach to the BAT validation are reasonable; however, with respect to certain parameters, the FDA is requesting additional data to further support ultimate determination of BAT validation.

W. Thomas Amick, Chairman of the Board and Chief Executive Officer of Discovery Labs commented, "We have made considerable progress towards the filing of a Surfaxin Complete Response. The work that we originally proposed to the FDA relating to the comprehensive preclinical program has been completed. We have generated data that demonstrate a meaningful reduction in variability in the optimized BAT and have conducted supportive side-by-side studies with the well-established pre-term lamb model of RDS. We appreciate the FDA's willingness to provide guidance and, based on our preliminary assessment, believe that we could generate the additional data and be in a position to file a Surfaxin Complete Response by early third quarter 2011."

Discovery Labs has conducted a comprehensive pre-clinical program employing an optimized BAT in a series of prospectively-designed, side-by-side preclinical studies with the well-established preterm lamb model of RDS. Discovery Labs engaged in several interactions with the FDA intended to ensure that the comprehensive preclinical program would satisfy the FDA. At the FDA's suggestion, Discovery Labs submitted a proposal seeking clarification regarding specific and detailed aspects of final BAT validation. To address certain technical criteria relating to final BAT validation, the FDA's recent correspondence advises Discovery Labs to increase the sample size of a specific data set by testing additional Surfaxin batches. Discovery Labs currently has data from batches that have already been manufactured and, to be responsive to the FDA's advice, anticipates manufacturing additional batches in January and February of this year.

Later this month, Discovery Labs expects to provide to the public a detailed overview of its program and anticipates holding a conference call.

DISCLOSURE NOTICE: The information in this press release includes certain "forward-looking" statements relating, among other things, to Discovery Labs' understanding of the recently-received written guidance from the FDA and the remaining questions identified in the FDA's April 2009 Complete Response Letter that must be addressed to gain FDA approval of Surfaxin. Although Discovery Labs currently believes that it may still succeed in submitting a Complete Response and gaining approval of its NDA for Surfaxin for the prevention of RDS in premature infants, anticipated activities will require that Discovery Labs raise significant amounts of additional capital. Discovery Labs has initiated activities relating to this most recent FDA communication and anticipates potential further interactions with the FDA in advance of filing a Complete Response. Such potential interactions with the FDA could affect the ultimate timing, conduct and outcomes of remaining steps necessary to gain Surfaxin approval, including the potential filing of the Complete Response. In addition, these activities and the ultimate outcomes remain subject to a variety of risks and uncertainties that could cause actual results to be materially different. These risks and uncertainties include, but are not limited to, risks that (i) the FDA may not approve Surfaxin or may subject the marketing of Surfaxin to onerous requirements that significantly impair marketing activities; (ii) Discovery Labs may be unable to complete the manufacture of additional Surfaxin batches within the time frame set forth above, (iii) Discovery Labs may identify unforeseen problems that have not yet been discovered or the FDA could in the future impose additional requirements to gain approval of Surfaxin; and (iv) Discovery Labs may be unable to raise sufficient additional capital, through financings, strategic collaborations, or otherwise. Any failure to satisfy the issues raised by the FDA, in the Complete Response letter or in related discussions, could significantly delay, or preclude outright, gaining approval of Surfaxin, which could potentially delay or prevent the approval of Discovery Labs' other products.

Surfaxin is an investigational drug product and is not approved by the FDA or any other world health regulatory authority for use in humans. If approved, Surfaxin would become the first synthetic, peptide-containing surfactant for commercial use in neonatal medicine.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing surfactant therapies for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs' novel proprietary KL4 surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, aerosol or lyophilized formulations. In addition, Discovery Labs' proprietary capillary aerosolization technology produces a dense aerosol, with a defined particle size that is capable of potentially delivering aerosolized KL4 surfactant to the lung without the complications currently associated with liquid surfactant administration. Discovery Labs believes that its proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of surfactant products to address a variety of respiratory diseases for which there frequently are few or no approved therapies. For more information, please visit our website at www.Discoverylabs.com.

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Examples of such risks and uncertainties, including those related to the Company's comprehensive non-clinical program, development and manufacturing activities and related regulatory efforts, are described in Discovery Labs' filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

Contact Information:
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